510(k) Summary of Safety and Effectiveness
for
MicroSurgeon, Inc
Microwave Tissue Ablation Device System

FEB 12 2009

1. DATE SUMMARY PREPARED:

January 2, 2009

2. SUBMITTER'S NAME AND ADDRESS:

MicroSurgeon, Inc
8489 West 3RD Street
Suite 1044
Los Angeles, CA 90048

3. CONTACT PERSON:

Mr. Dudley Harris
Quality & Regulatory Director
Telephone:(323) 801-2209
Facsimile: (310) 423-1008

4. DEVICE NAME:

Proprietary (trade) Name:	MicroSurgeon Tissue Ablation Device
Common Name:	Microwave ablation device
Classification Name:	System, ablation, microwave and accessories, CFR 878.4400
Product Code:	NEY
Class:	II
Panel:	General & Plastic Surgery

5. PREDICATE DEVICE:

The legally marketed device/s to which equivalence is being claimed is:

MicroSurgeon, Inc
8489 West 3RD Street
Suite 1044
Los Angeles, CA 90048

K070023: Microwave Ablation System & Accessories

6. DEVICE DESCRIPTION

The MicroSurgeon Microwave Tissue Ablation device model MTAD-200 is intended to be used by the physician for the ablation of soft tissue by the induction of thermal necrosis in the targeted tissue. The ablation occurs by direct application of microwave energy to the targeted tissue by use of a sterile hand held Disposable Patient Probe (DPP). Lesion sizes ablated by the system are determined by preset values within the system algorithm.

The MTAD-200 allows the physician to use a minimally invasive procedure that is an alternative to surgical removal of solid tissue anomalies. It is to be used in conjunction with the clinician's knowledge of the patient as well as the results of a physical examination along with clinical findings as deemed pertinent. The MTAD-200 system is not to be used by untrained and unqualified users in a manner other than that for which it is labeled.

The systems Microwave Generator Subsystem (MWGS) generates an RF 2.45GHz signal which is delivered to the Disposable Patient Probe DPP via related controlled electronics, and provides for required patient galvanic isolation. The MWGS component of the MTAD-200 was designed for exclusive use of, and to generate microwave energy to the patient disposable probe cited above.

The one time use sterile DPP Hand-piece incorporates a Tip that is inserted directly into the tissue for localized energy delivery, and acts as a microwave radiator in a bipolar mode; thus near-field radiated energy is contained within a limited field with no currents flowing into the patient (as opposed to uni-polar RF Radiators in which current flows thru the patient's body). Two independent Thermo-sensors (provided for further redundancy of the system) located at the tip of the DPP are used to provide for localized temperature measurement during the ablation process. The CPS utilizes these temperature measurements to control the delivery of energy in order to

achieve the desired ablation.

The CPS, running a Microsoft Windows Operating System, provides for profile programming onto a patient data file; provides user interface and controls the MWGS unit based on predetermined settings. All MWGS functionality and temperature measurements are processed and displayed by this unit, and utilized to achieve a desired ablation. Additionally, it stores all relevant patient information and measured parameters for the procedure.

Keyboard Functions
The MTAD-200 contains a full-function keyboard that can be used for input of patient data and for controlling specific system functions such as testing.

7. INDICATIONS FOR USE

The MicroSurgeon Microwave Tissue Ablation Device is intended to be used for the surgical ablation of soft tissue.

8. CLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The results of bench testing support the above indications for use as well as the claim of Substantial Equivalence to the predicate devices listed in item #5 above.

9. NON-CLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The substantial equivalence of the Microwave ablation system is also demonstrated by the following non-clinical testing to the following applicable standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety: Electromagnetic Compatibility (2004)
- IEC 60601-2-2: Particular Standard for the Safety of High Frequency Surgical Equipment, March, 2007 (2006).

The performance, functionality, and reliability characteristics of the device followed established test procedures, and a quality design system.

10. CONCLUSIONS FROM NON-CLINICAL TESTING

The MicroSurgeon Microwave Tissue Ablation device (MTAD-200) has completed the testing listed above with acceptable results, demonstrating substantial equivalence.

11. SUBSTANTIAL EQUIVALENCE CONCLUSION

In summary, Indications for Use, safety standards tested to, and the ablation performance data between the MicroSurgeon MTAD-200 system, and the predicate device listed in item #5 above shows nearly identical data. There are no new questions of safety or efficacy raised by the MTAD-200 system; therefore, the system supports a claim of Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MicroSurgeon, Inc.
% Mr. Dudley Harris
Quality & Regulatory Consultant
20363 Tulip Circle
Montrose, Colorado 81403

FEB 12 2009

Re: K082565
Trade/Device Name: MicroSurgeon Microwave Tissue Ablation Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY
Dated: January 7, 2009
Received: January 12, 2009

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David Krane

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MicroSurgeon, Inc

K082565

Indications for Use Statement

510(k) Number (if known): K082565

Device Name: MicroSurgeon Microwave Tissue Ablation Device

Model: MTAD-200

Indications for Use: The MicroSurgeon Microwave Tissue Ablation Device is intended to be used for the surgical ablation of soft tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR ~~Over-The-Counter~~ Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082565